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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,352	11/08/2000	Joan D. Leonard	02108.0001U2	1597

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EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	17

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/708,352	LEONARD ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *26 December 2002*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☒ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see Advisory Attachment*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *none*.

Claim(s) objected to: *none*.

Claim(s) rejected: *1-12 and 21*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *See Advisory Attachment.*

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER

Advisory Action Attachment

1. Applicant's amendment filed December 26, 2002 is acknowledged. Applicant's Declarations filed under 37 C.F.R. 1.132 (Dr. Wu and Dr. Field) filed December 26, 2002 is acknowledged.

2. Applicant's Declaration by Dr. Wu filed under 37 C.F.R. 1.132 is not sufficient to overcome the 103(a) rejection of record. The Declaration by Dr. Wu was submitted to show that the claimed biotypes differ from that of the prior art. The Declaration of Dr. Wu teaches that *Mycoplasma* biotypes A, B and C were determined by Restriction endonuclease analysis (REA). The specification teaches that "biotypes" are defined as variant of a species, i.e. a strain that can be distinguished by one or more characteristics such as ribosomal RNA sequence variation, DNA polymorphisms, serological typing or toxin production (page 5). Therefore, the claimed invention is not limited to the biotypes of A, B and C because the specification fails to define the characteristics of biotypes A, B and C. The specification teaches that other methods of biotyping *Mycoplasma* or other microorganisms are well known in the art and may be used to in the practice of the invention (page 14). The specification teaches that characterization and typing of field isolates were determined by PCR fingerprinting (page 12). The data presented in the Declaration of Dr. Wu cannot be used to overcome the rejection of record because the method used to determine the biotypes in the Declaration of Dr. Wu differs from the method used to determine the biotypes in the specification (PCR fingerprinting versus Restriction endonuclease analysis). Applicant

has not shown that the claimed biotypes differ from that of the prior art based on the method of determining biotypes used in the specification nor are biotypes defined in the specification or in the claims to be limited to a particular pattern. A direct comparison of biotypes determined by PCR fingerprinting and biotypes determined by REA cannot be made. The skilled artisan would obtain different biotyping information based on the method used to determine biotypes.

3. Applicant's Declaration by Dr. Field filed under 37 C.F.R. 1.132 is not sufficient to overcome the 102(b) rejection of record. The Declaration by Dr. Field was submitted to show that the vaccine composition of the prior art and the claimed vaccine composition differ in protein concentration. The Declaration by Dr. Field asserts that the claimed vaccine contains 1.84 x 10^9cell equivalents which correspond to approximately 6 micrograms of *M. bovis* protein and the vaccine of the prior art contained 500 micrograms. The Declaration by Dr. Field states that " the present vaccine differs from the Howard et al. in that it is significantly, i.e. ~500-1500 fold more dilute than the vaccine of Howard et al". It must be remembered that the claimed vaccine requires ...wherein the amount of each inactivated biotype is at least 10^8 *M. bovis* cell equivalents and ...wherein the attenuated biotype is at least 10^5 *M. bovis* cells. Applicant admits on page 3 of the Declaration by Dr. Field that Howard et al teaches 500 micrograms of *M. bovis* protein which corresponds to 1.5 x 10^{11} as described in Howard et al (page 373, 1st column). Therefore, Howard et al teach at least 10^5 *M. bovis* cells. Therefore, Howard et al anticipates the claimed vaccine.

4. In regard to Applicant's comments to rejection under 35 U.S.C. 112, first paragraph in the Final Rejection (paper 12, mailed June 18, 2002), the withdrawal of the rejection should have been for claims 1-12 instead of claims 5-12. The Office apologizes for the oversight.

5. Applicants amendment is not entered because claim 1 as amended would require further consideration and require new searches. Amended claim 1 is directed to a vaccine which is protective against *Mycoplasma bovis* clinical disease biotype and a pharmaceutically acceptable excipient and wherein the vaccine does not include saponin. The claim limitation "... wherein the vaccine does not include saponin..." has not been searched or considered.

Additionally, amended claim 1 and claims 2-12 (from which depend from claim 1) would raise new 112 issues. New issues would include a New Matter rejection under 35 U.S.C. 112, first paragraph for the negative limitation "...wherein the vaccine does not include saponin...".

6. The rejection of claims 1-4 and 21 under 35 U.S.C. 102(b) is maintained for the reasons of record as set forth in pages 2-4, paragraph 4 of the previous Office Action.

Claims 1-4 and 21 are directed to a vaccine which is protective against *Mycoplasma bovis* clinical disease in a bovine species comprising at least one

inactivated or attenuated *Mycoplasma bovis* biotype and a pharmaceutically acceptable excipient. Applicant's arguments are directed to the amended claims, which have not been entered.

7. The rejection of claims 5-12 under 35 U.S.C. 103(a) is maintained for the reasons of record as set forth in pages 4-6, paragraph 5 of the previous Office Action. Applicant's arguments are directed to the amended claims, which have not been entered.

Status of Claims

8. No claims are allowed.

Conclusion

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
April 25, 2003